

OPHTHALMIC DEVICES PANEL

One Hundred and Seventh Meeting
Gaithersburg Marriott
Gaithersburg, MD

FEBRUARY 5, 2004

PUBLIC AGENDA

9 A.M. – 5:00 P.M.

9:00	Call to Order	Jayne S. Weiss, M.D. - Chair
	Introductory Remarks	Sara M. Thornton - Executive Secretary
	Conflict of Interest Statement	
	Appointment to Temporary Voting Status	

9:15 – 9:45

OPEN PUBLIC HEARING

OPEN COMMITTEE SESSION

Jayne S. Weiss, M.D., Chair

9:45 – 10:00

DIVISION UPDATE

A. Ralph Rosenthal, M.D., Director

BRANCH UPDATES

James F. Saviola, O.D.

Chief, Vitreoretinal and Extraocular Devices Branch

Donna R. Lochner

Chief, Intraocular and Corneal Implants Branch

Everette T. Beers, Ph.D.

Chief, Diagnostic and Surgical Devices Branch

PMA P030028

10:00 – 11:30

SPONSOR PRESENTATION

Followed by
Questions and Answers

11:30 – 12:30pm

FDA PRESENTATION

Jeffrey Toy, Ph.D. – Team Leader
Bernard Lepri, O.D., M.S., M.Ed. – Clinical Reviewer
Gerry W. Gray, Ph.D. – Statistician

12:30 – 1:30

LUNCH

1:30 – 5 p.m.

COMMITTEE DELIBERATIONS

Panel Questions for FDA

Primary Panel Reviews

PANEL DISCUSSION OF PMA P030028
to include FDA questions to the Panel

30-MINUTE OPEN PUBLIC HEARING SESSION

FDA – CLOSING COMMENTS (5 minutes)

SPONSOR – CLOSING COMMENTS (5 minutes)

Voting Options Read

PANEL RECOMMENDATION TAKEN BY VOTE

POLLING OF PANEL VOTES

COMMENTS FROM CONSUMER AND INDUSTRY REPRESENTATIVES

FINAL PANEL COMMENTS

5:00p.m.

OPEN MEETING ADJOURNED

NOTE: 15-MIN. BREAKS MAY BE GIVEN AT APPROPRIATE TIMES DURING THE PROCEEDINGS